DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

December 18.2014

Impladent, Ltd.
Maurice Valen
President
198-45 Foothill Ave.
Holliswood, New York 11423

Re: K141764
Trade/Device Name: TriStar Bone Graft Fixation System
Regulation Number: 21 CFR 872.4760
Regulation Name: Bone Plate
Regulatory Class: Class II
Product Code: JEY, DZL
Dated: November 18, 2014
Received: November 19, 2014

Dear Mr. Valen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosures

Indications for Use

510(k) Number: **N/A** K141764

Device Name: **TriStar Bone Graft Fixation System**

Indications for Use:

The TriStar Bone Graft Fixation System is indicated for stabilization and fixation of bone grafts, bone blocks, bone filling materials, and / or barrier membranes used to regenerate bone in the oral cavity.

Prescription Use **YES** AND/OR Over-the-Counter **NO**

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)

K141764

510(k) Summary

Type of Submission:	Traditional Premarket Notification 510(k), 21 CFR 807.92
Submitted by:	Impladent Ltd. 198-45 Foothill Avenue Holliswood NY 11423-1611
Contact Person:	Maurice Valen, President; Director of R&D Andrew Valen, Vice President Phone: 718 465-1810 Fax: 718 464-9620 Email: maurice@impladentltd.com cc: andrew@impladentltd.com
Establishment Registration:	2431866
Common Name: Proprietary Name:	Titanium Fixation Screw System TriStar Bone Graft Fixation System
Classification:	Class II, 21 CFR 872.4760
Product Code: Review Panel:	JEY Dental
Confidentiality:	Under section 21 CFR 807.95, selected pages and/or sections have been marked as "CONFIDENTIAL"
Purpose of Submission:	New device. Evidence herein is submitted to establish substantial equivalence for the TriStar Bone Graft Fixation System
Predicate Devices Screws:	Salvin Titanium Fixation Screw System (K073342) Frontier Devices Maxillofacial and Mesh System (K091812) BioPlate Rigid Fixation Bone Plating System for Craniomaxillofacial Surgery (K030806, K972463, K022890) Alpha-Bio Tec Bone Fixation Screw System (K063769)
Predicate Devices Mesh:	Unicare Biomedical Cytoflex Mesh (K021511)

510(k) Summary

Device Description:

The TriStar Bone Graft Fixation System consists of titanium alloy self-drilling screws which are tapered and have a maximum diameter of 1.75mm with lengths of 3mm, 4mm, 5mm, 6mm, 8mm, 10mm, 12mm, 14mm, 15mm, 18mm, 21mm, and 24mm. The screws are manufactured using a Ti-6Al-4V alloy (ASTM F-136) and adhere to standards tested under ASTM F-543. This system also includes a number of accessories used to fixate the screws and/or membranes or bone blocks to the host bone including a square headed morse tapered hand screw driver, screw driver handle, and latch type driver. The system includes titanium mesh in 40mm x 60mm or 18mm x 25mm sizes each having a thickness of 0.1mm. The screws and titanium mesh are designed to be removed from the patient after such time when sufficient bone regeneration is demonstrated. The devices are sold non-sterile. Single use only.

Indications for Use:

The TriStar Bone Graft Fixation System is indicated for stabilization and fixation of bone grafts, bone blocks, bone filling materials, and / or barrier membranes used to regenerate bone in the oral cavity.

Technological Characteristics & Substantial Equivalence

As was established in this submission, the subject device is substantially equivalent to other devices cleared by the FDA for commercial distribution. Engineering drawings, labeling, advertising materials and mechanical testing have been submitted and demonstrate that the subject device is substantially equivalent to its predicate devices in terms of design, material composition, indications for use, standards applied and other characteristics. There are no unique applications, indications, materials or specifications for the TriStar Bone Graft Fixation System when compared to the predicate devices.

Testing

Non-clinical performance testing has been conducted using ASTM F543-13 – Standard Specification and Test Methods for Metallic Medical Bone Screws. Mesh was tested under ASTM F382. Tests from these standard were also conducted on the predicate devices. Clinical testing is not applicable to this device. Biocompatibility of the patient contacting titanium devices has been tested under ISO 10993-5 and found to be biocompatible.

Conclusion

Based on the 510(k) Summary and the information provided in this submission, we conclude that the TriStar Bone Graft Fixation System is substantially equivalent to the existing legally marketed devices cited above and where minor differences exist, these differences raise no new safety, effectiveness and/or performance issues.

Substantial Equivalence Predicate Device Table - Screws

Device	**TriStar Bone Graft Fixation System**	**Salvin Dental Specialties Titanium Fixation Screw System**	**Frontier Devices Maxillofacial and Mesh System**	**BioPlate Rigid Fixation Bone Plating System for Craniomaxillofacial Surgery**	**Alpha-Bio Tec Bone Fixation Screw System**
510(k) Number	K141764	K073342	K091812	K030806, K972463, K022890	K063769
Applicant Name	Impladent Ltd.	Salvin Dental Specialties	Frontier Devices	BioPlate	Alpha-Bio
Year 510(k) Cleared	2014	2008	2010	1997, 2002, 2003	2007
Screw Design	Self-Drilling	Self-Tapping	Self-Drilling & Self-Tapping	Self-Drilling	Self-Tapping
Screw Material	Ti-6Al-4V (ASTM F-136)	Ti-6Al-4V	Ti-6Al-4V (ASTM F-136)	Ti-6Al-4V	Ti-6Al-4V (ASTM F-136)
Head Configuration	Square	Cross	Cross	Square	Hexagonal
Screw Length	3mm – 24mm	4mm – 15mm	3mm – 24mm	3mm – 10mm	4mm – 12mm
Screw Diameter	1.75mm max	1.5 & 2.0 mm	1.5 – 2.3 mm	1.5, 1.8, 1.9, 2.3 mm	1.2, 1.6mm
Mesh Offered	Yes	Yes	Yes	Yes	No
Plates Offered	No	No	Yes	Yes	No
Bench Testing	ASTM F-543	ASTM F-543	Not Specified	Not Specified	Not Specified
Indications for Use	The TriStar Bone Graft Fixation System is indicated for stabilization and fixation of bone grafts, bone blocks, bone filling materials, and / or barrier membranes used to regenerate bone in the oral cavity.	The Salvin Dental Specialties, Inc. Titanium Fixation Screw is intended for use in internal fixation of small bones including the craniofacial and maxillofacial skeleton affected by trauma, or for reconstruction.	Frontier Devices Maxillofacial System is intended for use in selective trauma of the mid-face and maxillofacial skeleton; maxillofacial surgery; reconstructive procedures; and selective orthognathic surgery of the maxilla and chin.	The Bioplate Rigid Fixation Bone Plating System for Craniomaxillofacial Surgery is intended for use in the treatment of fractures and reconstructive procedures of the Craniomaxillofacial skeleton and non-weight bearing fixation, including cranial bone fixation, brow fixation, and orbital fixation. Each device is intended for single use only and only in conjunction with other titanium and titanium alloy implants.	The Alpha-Bio Bone Fixation Screw System is indicated to stabilize and fixate bone grafts, bone filling materials, and / or barrier membranes used for regeneration of bone in the oral cavity.
Marketed As Kit	Yes	Yes	Yes	Yes	Yes
Items in Kit	Screws Handle Driver Mesh	Cassette Screws Handle Driver Drill Additional Drill	Cassette Screws Handle Driver Mesh Mesh Cutter Ti-Plates	Cassette Screws Handle Driver Foreceps Ti-Plates	Screws Driver Drill
Sterilization	Steam	Steam	Steam	Steam	n/a
Product Code / Regulation #	JEY 872.4760	DZL 872.4880	DZL 872.4880	JEY 872.4760	DZL 872.4880

Substantial Equivalence Predicate Device Table - Mesh

Device	**TriStar Bone Graft Fixation System Titanium Mesh**	**Unicare Biomedical Cytoflex Mesh**
510(k) Number	K141764	K021511
Classification	JEY	JEY
Material	Grade 1 Titanium	Commercially Pure Titanium
Specification	Bending tests as per ASTM F 382-99 (R2008)	Bending tests as per ASTM F 382-99 (R2008)
Dimensions	(1) 18 x 25 mm (2) 40 x 60 mm	(1) 25 x 30mm
Thickness	0.1 mm	0.1 mm
Size of holes	0.8 mm	0.5 mm
Biocompatibility	Cytotoxicity	Unknown
Indications	Stabilization and fixation of bone grafts, bone blocks, bone filling materials, and / or barrier membranes used to regenerate bone in the oral cavity. [These are the same indications as kit overall]	Used to ensure three dimensional reconstruction of alveolar bone defects and to facilitation augmentation with adequate fixation of the augmentation material.